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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/712,821	11/13/2000	Todd M. Kinsella	A-70036/RMS/JJD	9149

959 7590 11/26/2002

LAHIVE & COCKFIELD
28 STATE STREET
BOSTON, MA 02109

EXAMINER

PONNALURI, PADMASHRI

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 11/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Restriction Purposes only

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Application No.
09/712,821

Applicant(s)

Kinsella

Examiner
Padmeshri Ponnaluri

Art Unit
1639



Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 5/10/02 and 8/19/02
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-37 is/are pending in the application.
- 4a) Of the above, claim(s) 7-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 13-37 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

Art Unit: 1639

DETAILED ACTION

NOTE: The Group and/or Art Unit location and Examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to **Group Art Unit 1639**.

1. Applicant's request for reconsideration of the preliminary amendment filed on 5/10/02 which crossed in the mail is persuasive and, therefore, the previous office action mailed on 6/4/02 is withdrawn.
2. The preliminary amendment B, filed on 5/10/02; and the Request for issuance of revised office action filed on 8/19/02 has been fully considered and entered into the application.
3. Claims 1-6 have been canceled and new claims 13-37 have been added by the amendment B, filed on 5/10/02.
4. Claims 7-37 are currently pending in this application.
5. Claims 7-12 are withdrawn from further consideration pursuant to 37 CAR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 9, filed on 4/3/02.

Please Note: In an effort to enhance communication with our customers and reduce processing time, a dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action

Art Unit: 1639

for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Andrew Wang, Supervisory Patent Examiner at andrew.wang@uspto.gov or 7(703)306-3217. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

Election/Restriction

6. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 13-20, 25-31, 34-37, drawn to an expression vector comprising nucleic acid encoding HBEGF and GFP, classified in class 435, subclass 320.1.
 - II. Claims 21-24, 32-33, drawn to an expression vector comprising nucleic acid encoding a HBEGF and nucleic acid encoding IRES site, classified in class 435, subclass 320.1.
7. The inventions are distinct, each from the other because of the following reasons:
8. Inventions of group I and group II are distinct from each other. Group I and Group II inventions are distinct from each other because they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of group I are drawn to an expression vector comprising nucleic acid encoding HBEGF and GFP; and group II inventions

Art Unit: 1639

are drawn to an expression vector comprising nucleic acid encoding HBEGF and nucleic acid encoding an IRES site. Thus the inventions of Group I and Group II are structurally and functionally distinct from each other and restriction between the groups is proper.

9. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, and have acquired a separate status in the art because of their recognized divergent subject matter restriction for examination purposes as indicated is proper.

Even though the groups are classified in the same class/subclass, this has no effect on the non-patent literature search. Different groups would require completely different searches in non-patent databases, and there is no exception that the searches would be co-extensive. Therefore, these do not create an undue search burden, and restriction for examination purposes as indicated is proper.

10. This application contains claims directed to the following patentably distinct species of the claimed invention:

Applicants are requested to elect a single species for each of the following:

- a) either 2a site or CD9 site;
- b) one single species of selection gene ;
- c) one single species of GFP;

Art Unit: 1639

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CAR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

11. **For this response to be complete and for search purposes,** Applicant is required under 35 U.S.C. 121 to **elect a single invention** (i.e., single expression vector, in which the specific components are all defined; and the relationship between the components (position and/or order

Art Unit: 1639

of arrangement) **wherein each of the elected expression vector includes each of the above identified elected species** for prosecution on the merits..

12. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CAR 1.143).

Applicant is advised that a reply to this requirement must include an identification of the invention that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added.

Should applicant traverse on the ground that the method inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the method inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

13. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CAR 1.143).

Art Unit: 1639

Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Ponnaluri whose telephone number is (703) 305-3884. The examiner is on *Increased Flex Schedule* and can normally be reached on Monday to Friday from 7.00 AM to 3.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

P. Ponnaluri
Patent Examiner
Technology Center 1600
Art Unit 1639
12 November 2002


PADMASHRI PONNALURI
PRIMARY EXAMINER



RESTRICTION ELECTION FACSIMILE TRANSMISSION

DATE:

FROM/ATTORNEY:

FIRM:

PAGES, INCLUDING COVERSHEET:

PHONE NUMBER:

TO EXAMINER: P. Ponnaluri

ART UNIT: 1639

SERIAL NUMBER: 09/712,821

FAX/TELECOPIER NUMBER: (703) 308-4315

**PLEASE NOTE: THIS FACSIMILE NUMBER IS TO BE USED ONLY
FOR RESPONSES TO RESTRICTIONS.**

COMMENTS: _____

IF YOU HAVE NOT RECEIVED ALL THE PAGES OF THIS TRANSMISSION, PLEASE CONTACT THE ATTORNEY AT THE TELEPHONE NUMBER LISTED ABOVE.

IN COMPLIANCE WITH 1096 OG 30, THE FILING DATE ACCORDED EACH OFFICIAL FAX TRANSMISSION WILL BE DETERMINED BY THE FAX MACHINE DATE STAMP FOUND ON THE LAST PAGE OF THE TRANSMISSION, UNLESS THAT DATE IS A SATURDAY, SUNDAY, OR FEDERAL HOLIDAY WITHIN THE DISTRICT OF COLUMBIA, IN WHICH CASE THE OFFICIAL DATE OF RECEIPT WILL BE THE NEXT BUSINESS DAY.

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